REMICALM LLC

952 Echo Lane, Suite 333 Houston, TX 77024
Voice: 713-984-8550 Fax: 713-984-9232

K090135

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## V. 510(k) SUMMARY

Submitted by: TRIMIRA LLC
952 Echo Lane
Houston, TX 77024
Phone: (713) 984-8550
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FEB 17 2009

Contact Person: David B. Jones

Date Prepared: January 20, 2009

Proprietary Name: **TRIMIRA™ Identafi™ 3000**

Common Name: Oral Examination Light and Accessories

Classification:

| | |
|---|---|
| Class II: | 21 CFR § 872.6350 |
| Class I: (Exempt) | 21 CFR § 874.4420 |
| Class I: (Exempt) | 21 CFR § 886.5850 |

Classification Name: Ultraviolet Detector – NXV (EAQ)
ENT manual surgical instrument (Mirrors) – KAI (Exempt)
Filtered glasses – HQY (Exempt)

Predicate Devices: Trimira OCS 3000 (K082603)
952 Echo Lane #333
Houston, TX 77024

Device Description:

The **TRIMIRA™ IDENTAFI 3000®** is a "AA" battery operated, hand-held, multispectral oral examination light used in conventional and specialized oral examination. Accessories include safety glasses and disposable mirrors.

Intended Use:

**Identafi™ 3000** is intended to be used by qualified health-care providers to enhance the identification and visualization of oral mucosal abnormalities that may not be apparent or visible to the naked eye, such as oral cancer or premalignant dysplasia.

**Identafi™ 3000** allows for conventional oral mucosal examination and excites the tissue with multispectral lights for direct visualization of the resulting natural tissue fluorescence and reflectance, and vasculature.

**Identafi™ 3000** is also intended to be used by a surgeon to help identify diseased tissue around a clinically apparent lesion to aid in determining the appropriate margin for surgical excision.

**Identafi™ 3000** eyewear is reusable filtered eyewear that is worn by a health care professional to enhance the visual effects of violet light during oral exam. **Identafi™ 3000** eyewear has been designed to allow transmission of 430-580 nm light.

Technological Characteristics:

The Identafi™ 3000, with multispectral identifi™ technology (patents pending), uses "AA" batteries to operate high-intensity LEDs to produce white, violet and amber light. These safe, visible lights allow health professional to perform Conventional Oral Examination (COE) using white light, and specialized or enhanced visual examinations of tissue using violet and amber lights.

The Identafi™ 3000 violet light enhances normal tissue's natural fluorescence. Visual examination under violet light shows healthy tissues fluorescing blue (when using rose colored filtered glasses)

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while suspicious tissue appears dark because of its loss of fluorescence. Amber light enhances the tissue's natural reflectance and makes visualization of the vasculature possible.

The direct visualization of fluorescent and reflective tissues is using the body's natural system to identify suspicious tissue quickly that may require further investigation. The loss of natural tissue fluorescence and reflectance can identify subclinical high-risk fields with cancerous and precancerous changes Clinical Cancer Research Vol. 12, 6716-6722, November 15, 2006.

Substantial Equivalence

The Identafi™ 3000 has the same intended use and technological characteristics as the approved predicate device, Trimira™ OCS 3000, K082603. Each uses fluorescence and/or reflectance as the primary mode for enhanced visualization of tissue for determining oral tissue abnormalities.

The design, materials, method of operation, and labeling are substantially equivalent.

The TRIMIRA™ Identafi™ 3000 is substantially equivalent to the approved predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2009

Mr. David B. Jones
Vice President, Regulatory Affairs and Quality Assurance
Remicalm, LLC
952 Echo Lane, Suite 333
Houston, Texas 77024

Re: K090135
Trade/Device Name: TRIMIRA™ Identafi™ 3000
Regulation Number: 21 CFR 872.6350
Regulation Name: Ultraviolet Detector
Regulatory Class: II
Product Code: NXV
Dated: February 10, 2009
Received: February 11, 2009

Dear Mr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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## IV. Indications for Use

Applicant: TRIMIRA LLC
952 Echo Lane, Suite 333
Houston, TX 77024
Phone: (713) 984-8550
Fax: (713) 984-9232

510(k) Number (if Known): _____

Device Name: **TRIMIRA™ Identafi 3000™**

Indications For Use:

**Identafi™ 3000** is intended to be used by qualified health-care providers to enhance the identification and visualization of oral mucosal abnormalities that may not be apparent or visible to the naked eye, such as oral cancer or premalignant dysplasia.
**Identafi™ 3000** allows for conventional oral mucosal examination and excites the tissue with multispectral lights for direct visualization of the resulting natural tissue fluorescence and reflectance, and vasculature.
**Identafi™ 3000** is also intended to be used by a surgeon to help identify diseased tissue around a clinically apparent lesion to aid in determining the appropriate margin for surgical excision.
**Identafi™ 3000** eyewear is reusable filtered eyewear that is worn by a health care professional to enhance the visual effects of violet light during oral exam. **Identafi™ 3000** eyewear has been designed to allow transmission of 430-580 nm light.

Prescription Use ✓ AND/OR Over-the-Counter _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090135